

**Patient package insert in accordance with the
Pharmacists' Regulations - (Preparations) - 1986**

Non-prescription medicine

Clean-Af

Nose drops

Composition: Active substances and their concentration:

Sodium Chloride 0.9% w/v

For the list of the inactive substances: See Section 6 "Additional information". Read the insert carefully to the end before using the medication. This insert contains abridged information on the medicine. If you have further questions, consult your doctor or pharmacist.

Use the preparation correctly. Consult your pharmacist if you require additional information. **If the symptoms become more serious or do not improve after 3 days, consult your doctor.**

1. What the medicine is used for ?

For relief of nasal congestion in infants and toddlers.

Therapeutic Group - Saline solution

2. Before using the medicine

X **Do not use the medicine:** If you or your child are sensitive
• (allergic) to the active substance or to any of the additional ingredients contained in the medicine. For the list of the inactive substances - see Section 6 "Additional information".

I **Special warnings concerning use of the medicine:**

• **Consult your physician before starting the treatment:**

- If you or your child are suffering or have suffered in the past from:
 - Cardiac and/or vascular dysfunction, high blood pressure
 - Liver dysfunction
- If you are sensitive to any food or medicine.

- Do not use this medicine frequently, or for a long period, without consulting a physician.

I **If you are taking, or recently took, other medicines, including over the counter medicines and dietary supplements, inform your doctor or pharmacist. Important information about some of the ingredients of the medicine.**

The medicine contains benzalkonium chloride which might cause irritation in the nasal mucous membrane.

I **Pregnancy and Breast-feeding:**

You can use the medicine if you are pregnant or breast-feeding.

3. How to use the medicine?

Ask your doctor or pharmacist if you are not sure how to use it.

Manner of use: • Gently blow the nose. With the child standing or sitting, tilt his head back, or have him lie down and turn his head to the side.

Place the drops in each of the nostrils, and keep his head tilted back for a few minutes to allow the medicine to be distributed in the nasal cavity.

- Rinse the dropper with hot water and dry with a clean paper tissue.

Close the bottle tightly after use. In order to prevent spread of the infection, do not use the same bottle of medicine for more than one child.

Dosage: Recommended dosage unless otherwise instructed by the doctor: 2 drops in each nostril, 1-4 times a day. **Do not exceed the recommended dosage.** If there is no improvement in the condition within 3 days, consult your physician. **N.B.!** Do not swallow. This medicine is for nasal use.

Do not use in the eyes. If you have **accidentally** taken an overdose or if a child has accidentally swallowed the medicine, go immediately to a doctor or a hospital emergency room and bring the medicine package with you. If you forgot to take this medicine at the set time, take it as soon as you remember; but never take two doses together! Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them. If you have further questions concerning use of the medicine refer to your doctor or pharmacist.

The medicine refer to your doctor or pharmacist.

4. Side Effects:

As for any medicine, the use of Clean-Af may cause side effects in some users, such as irritation or a temporary burning sensation in the nose. Do not be alarmed by the list of side effects. You will probably not suffer from any of them.

Stop treatment and refer to your doctor:

- In the event of high blood pressure (for instance red face)
- In the event of itching or local inflammation (that did not exist before use of this preparation) (rare).

I **Side Effects in Children and Infants:** Parents must inform the attending physician of any side effect and any other medicine being taken by the child. See above for details of special side effects.

If a side effect appears, if one of the side effects becomes more serious, or you suffer from a side effect not mentioned in the insert, consult your doctor.

Reporting Side Effects:

You can report side effects to the Ministry of Health through the online form for reporting side effects that you will find on the homepage of the Ministry of Health website: www.health.gov.il

or by entry to the link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. How to store the medicine?

• **Avoid poisoning!** This medicine and all other medicine must be stored in a safe place out of the reach of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

- Do not use the medicine after the expiry date appearing on the package.

The expiry date refers to the last day of that month.

- Store in a cool place, below 25°C.
- Close tightly to prevent entry of air and damp.
- Store in the original package.
- You can use this medicine for one month from the time of opening.

Do not use this medicine if you notice a color change in the solution or if it becomes turbid.

6. Additional information

In addition to the active substances the medicine also contains:

Purified Water, Benzalkonium Chloride Sol.

Appearance of the medicine and contents of the package:

Transparent liquid **Contents:** 10 ml, 20 ml

Manufacturer and Reg. Owner: Ben-Shimon Floris Ltd., Misgav Industrial Park, D.N. Misgav 2017400.

This leaflet was inspected and approved by the Ministry of Health on: August , 2015.

Registration No. of the medicine in the National Drug Register of the Ministry of Health: 112 11 29492 00.